In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 16-1552V
Filed: September 14, 2018
PUBLISHED

MONICA PORTEE, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Special Processing Unit (SPU); Ruling on Entitlement; Causation-In-Fact; Findings of Fact Regarding Onset; Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Shealene Priscilla Wasserman, Muller Brazil, LLP, Dresher, PA, for petitioner.
Ann Donohue Martin, U.S. Department of Justice, Washington, DC, for respondent.

FINDINGS OF FACT AND RULING ON ENTITLEMENT[1]

Dorsey, Chief Special Master:

On November 21, 2016, petitioner filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*,[2] (the "Vaccine Act"). Petitioner alleges that she suffered a right shoulder injury caused in fact by the influenza vaccination she received on October 8, 2015. Petition at 1, ¶¶ 2, 11 (ECF No. 1). The case was assigned to the Special Processing Unit of the Office of Special Masters.

[1] The undersigned intends to post this ruling on the United States Court of Federal Claims' website. **This means the ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access. Because this published ruling contains a reasoned explanation for the action in this case, undersigned is required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services).

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

On April 25, 2018, petitioner filed a motion for a ruling on the record, arguing she "has provided evidence that satisfies her burden of proof . . . and is therefore entitled to compensation." Petitioner's Motion for a Ruling on the Record ("Pet. Motion") at 1 (ECF No. 41). For the reasons described below, the undersigned grants petitioner's motion and finds that petitioner is entitled to compensation.

I. Procedural History

Along with the petition, petitioner filed the medical records required by the undersigned's initial order. *See* Exhibits 1-4; Statement of Completion, filed Dec. 5, 2016 (ECF No. 7). The initial status conference was held on January 5, 2017, and respondent was ordered to file a status report indicating his tentative position regarding the merits of petitioner's case. *See* Order, issued Jan. 6, 2017 (ECF No. 8).

On April 5, 2017, respondent filed a status report indicating he was "willing to engage in settlement discussions with petitioner." (ECF No. 11). During the subsequent ten months, the parties engaged in settlement negotiations, and petitioner filed updated medical records. *See* Exhibits 5-9 (ECF Nos. 17 & 26).

On January 23, 2018, petitioner filed a status report requesting a status conference as the parties had "reached an impasse during settlement discussions." (ECF No. 34). During the status conference held on February 1, 2018, the parties agreed that the preferred course was for respondent to file a Rule 4(c) report setting forth his objections and for petitioner to file any additional evidence and a motion for a ruling on the record thereafter. *See* Order, issued Feb. 8, 2018 (ECF No. 35).

On March 13, 2018, respondent filed his Rule 4(c) report, arguing that compensation is not appropriate in this case. (ECF No. 36); *see infra* Section III (for a discussion of the specific objections raised by respondent and petitioner's response to those objections). Petitioner was ordered to file, along with her motion for a ruling on the record, a detailed affidavit describing the onset and progression of her condition. *See* Order, issued Mar. 23, 2018 (ECF No. 37). Attached to that order, the undersigned filed two articles pertaining to causation of vaccine-related shoulder injuries, known as shoulder injury related to vaccine administration ("SIRVA"). *See* Court Exhibits I-II. These articles, which were discussed by the Secretary when proposing the inclusion of SIRVA on the Vaccine Injury Table ("Table"),[3] are as follows: S. Atanasoff et al., *Shoulder injury related to vaccine administration (SIRVA)*, 28 Vaccine 8049 (2010), filed as Court Exhibit I, and M. Bodor and E. Montalvo, *Vaccination Related Shoulder Dysfunction*, 25 Vaccine 585 (2007), filed as Court Exhibit II.

[3] *See* National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 Fed. Reg. 45132, 45136 (July 29, 2015) (to be codified at 42 C.F.R. Part 100).

During the month of April 2018, petitioner filed her affidavit, additional updated medical records, several witness affidavits and other documentation, and her motion for a ruling on the record. (ECF Nos. 38-41). On May 9, 2018, respondent filed a response. (ECF No. 42). No reply was filed by petitioner.

Petitioner's motion for a ruling on the written record is now ripe for adjudication.

II. Factual History

The medical records from petitioner's primary care provider ("PCP"), Dr. Fitzgibbon, show that, prior to vaccination, petitioner suffered routine illnesses such as a sore throat, rhinitis, gastroesophageal reflux, and abdominal pain. Exhibit 2 at 6-39. At an April 21, 2014 visit, Dr. Fitzgibbon noted petitioner had gone to the emergency room due to a "fibromyalgia flair." *Id.* at 18. Petitioner was described as suffering some numbness in her arms and legs, but mostly her left arm. *Id.* However, by her next visit, on May 21, 2014, petitioner reported her that "her body aches and pains [were] gone." *Id.* at 21. Approximately one year later, on June 24, 2015, petitioner's fibromyalgia was listed as resolved. *Id.* at 28.

Petitioner also reported right elbow and wrist tendonitis when being treated for a urinary tract infection on June 23, 2014. Exhibit 2 at 24. There is no further reference to tendonitis in that record or any other record from prior to vaccination. In a later medical record, it is noted that petitioner performs "a lot of sedentary work and typing" at her job. Exhibit 3 at 11.

At a general exam performed on September 3, 2015, petitioner's health was described as good. Exhibit 2 at 36. No pain was noted under the musculoskeletal review. *Id.*

Petitioner received the vaccination alleged as causal on October 8, 2015, at her workplace, BlueCross BlueShield of North Carolina. Exhibit 1. The record of vaccination indicates petitioner received 0.5 mL of Flucelvax.[4] A lot number and expiration date were provided, but the record does not identify the arm in which the vaccination was administered. Exhibit 1.

Petitioner was seen by her PCP on November 5, 2015, for pain in her right deltoid after an influenza vaccination in early October 2015.[5] Exhibit 2 at 40. The right

[4] Flucelvax is a flu shot, manufactured by Sequris, Inc. in Holly Springs, North Carolina, which protects against three strains of influenza. Sequris, Inc. also manufactures Flucelvax Quadravalent which protects against four strains of influenza. *See* https://www.flucelvax.com/flucelvax-quadrivalent (last visited on Aug. 17, 2018).

[5] The medical record indicates petitioner received the vaccination at a pharmacy, but this information appears to be erroneous. *Compare* Exhibit 2 at 40 *with* Exhibit 1.

shoulder pain was described as a new issue. At that visit, it was noted that petitioner had "no neck pains or numbness or pains below her elbow." *Id.* Upon examination, petitioner showed normal range of motion ("ROM") and strength, no swelling or deformity, and "point pain in [the] insertion area of [her] right deltoid." *Id.* Dr. Fitzgibbon diagnosed petitioner with deltoid tendinitis and neuralgia, ordered x-rays, and prescribed prednisone. *Id.*

At some point during the subsequent month, it appears Dr. Fitzgibbon also ordered an MRI and referred petitioner to Dr. Fulton at Palmetto Health Orthopedics. *See* Exhibit 3 at 11 (first visit on January 19, 2016 to Dr. Fulton with referral noted); Exhibit 7 at 17[6] (results of a December 2, 2015 MRI ordered by Dr. Fitzgibbon). The MRI showed a partial thickness tear of the articular surface of the supraspinatus tendon, moderate subacromial/subdeltoid bursitis, and mild degenerative changes. Exhibit 7 at 7; *see also* Exhibit 3 at 11 (Dr. Fulton's summary of the MRI results).

On January 19, 2016, petitioner was seen by Dr. Fulton for "chronic pain in [her] right shoulder." Exhibit 3 at 11. Petitioner reported a "fairly acute onset of pain in the right shoulder" after receiving the influenza vaccination at her workplace in early October 2015, describing her pain as "sharp and persistent ever since the injection." *Id.* She also reported "popping in her shoulder," "loss of motion," and "night pain." *Id.* During examination, Dr. Fulton noted that petitioner had limited active and passive motion, painful movement, and no sign of bruising, redness, or swelling. He reviewed petitioner's MRI and diagnosed her with right frozen shoulder. He administered an injection in petitioner's glenohumeral joint, prescribed physical therapy ("PT"), and recommended petitioner take anti-inflammatories, apply ice, and perform stretching exercises. *Id.*

Petitioner began PT at Palmetto Health Orthopedic Rehab on February 2, 2016. At that initial visit, it was noted that her diagnosis was adhesive capsulitis of the right shoulder. Exhibit 4 at 23. She presented with increased pain and decreased ROM. The physical therapist recommended that petitioner attend PT twice weekly for eight weeks. *Id.* However, it appears petitioner attended only four weeks of PT, twice weekly for all but one week when petitioner attended only one PT session. *Id.* at 7-22.

Petitioner was seen again by Dr. Fulton on March 1, 2016. At that visit, she indicated that she "continue[d] to have rather frequent sharp pain in the shoulder . . . [which] has not improved much over time, [but] [h]er motion has improved some with therapy." Exhibit 3 at 9. It was noted that petitioner's PT had been interrupted after her son was in a motor vehicle accident ("MVA"). *Id.* After examining petitioner, Dr. Fulton

[6] Because petitioner did not label the individual pages in Exhibit 7 with exhibit and page numbers, the undersigned will use the page number listed in the CM/ECF heading to identify the particular page referenced.

described her ROM as improved. He recommended that petitioner continue her stretching. *Id.* at 10. On March 10, 2016, petitioner was discharged from PT after requesting to rely on a home exercise program ("HEP"), due to her son's MVA and her busy work schedule. Exhibit 4 at 6.

Petitioner next saw Dr. Fulton on April 12, 2016. She reported ongoing stiffness and pain, little relief from the earlier injection, incomplete relief from Tramadol,[7] and a lack of response to PT. Exhibit 3 at 8. Petitioner admitted she was "not doing her exercise program." *Id.* Dr. Fulton noted petitioner's slow improvement and recommended that she continue with her HEP. He added that petitioner should consider manipulation under anesthesia or arthroscopic surgery if she was did not "feel fully better within the next six weeks." *Id.*

Petitioner was not seen again by Dr. Fulton until almost a year later, on March 7, 2017, when she reported "a gradual worsening of shoulder pain over the last few months." Exhibit 5 at 20.[8] Dr. Fulton described her earlier frozen shoulder as "resolved with a long course of conservative treatment." *Id.* He indicated petitioner "was doing well for a while and redeveloped shoulder pain." *Id.* After re-reviewing petitioner's previous MRI and performing a physical exam, Dr. Fulton assessed petitioner with "[r]ecurrent right shoulder pain." *Id.* While noting that petitioner no longer suffered from a frozen shoulder, Dr. Fulton concluded "her problem appears to be chronic impingement from her acromion and AC joint, as well as [a] partial bursal tear of her cuff." *Id.* After discussing several options, petitioner consented to arthroscopic surgery. *Id.*

During the second half of 2016 and early part of 2017, petitioner visited her PCP, Dr. Fitzgibbon, for a variety of reasons, such as acute sinusitis, gynecological exam, and sore throat and cough. There is no mention of shoulder pain in the medical records from these visits, even a visit which occurred on March 11, 2017, four days after petitioner was seen by Dr. Fulton. *See* Exhibit 7 at 2-16. Additionally, the description of petitioner's musculoskeletal system in these records is limited to petitioner's gait, indicating it was normal. Thus, it appears that Dr. Fitzgibbon may have deferred mention of petitioner's shoulder condition given her treatment by Dr. Fulton.

On March 28, 2017, petitioner underwent a pre-operation physical conducted by Jessamyn Bartley, a physician's assistant ("PA") in Dr. Fulton's practice. Exhibit 5 at 10-14. The arthroscopic surgery, which involved subacromial decompression and a

[7] "Tramadol is a narcotic-like pain reliever . . . used to treat moderate to severe pain." https://www.drugs.com/tramadol.html (last visited Aug. 17, 2018).

[8] Like Exhibit 7, petitioner did not label the individual pages in Exhibit 5 with exhibit and page numbers. *See supra* note 6. Thus, the undersigned will use the page number listed in the CM/ECF heading to identify the particular page referenced in Exhibit 5.

distal clavicular excision, was performed by Dr. Fulton on April 6, 2017. *Id.* at 3-4. An interscalene nerve block and general anesthesia were administered. *Id.* at 3; *see also id.* at 8 (for a further description of the interscalene nerve block). Inserting the scope into petitioner's glenohumeral joint, Dr. Fulton observed that petitioner's cartilage, muscle, and rotator cuff appeared to be intact. *Id.* at 3. He performed a bursectomy[9] and removed a centimeter of the distal clavicle to decompress the joint. *Id.* 3-4. After examining the rotator cuff and again finding it intact, Dr. Fulton irrigated and closed the incision site. *Id.* at 4.

Petitioner was seen postoperatively on April 18, 2017. Exhibit 5 at 14-17. She stated that "she already [felt] better than she did before surgery and ha[d] taken only 2 days of pain medicine after the surgery." *Id.* at 16. Petitioner reported that she had been performing exercises from her previous PT and "feels like she is progressing nicely." *Id.* Petitioner attended 19 formal PT sessions from April 24 through May 8, 2017. *See* Exhibit 6 at 24[10] (June 16, 2018 summary); at 1-19 (for notes from individual sessions). In the June 16, 2016 summary, it was noted that petitioner continued to have pain. *Id.* at 24.

Petitioner had another follow-up appointment with Dr. Fulton on June 20, 2017. At that visit, she indicated that she was still symptomatic, adding that she may have re-injured her shoulder when lifting light grocery bags a few weeks earlier. Exhibit 12 at 8. She reported difficulty "picking up even light objects," and informed Dr. Fulton that "her physical therapist told her that she ha[d] muscle tightness and possible inflammation." *Id.* Dr. Fulton recommended that petitioner continue her formal PT and engage in aggressive daily stretching at home. *Id.* at 9. Petitioner attended additional PT sessions from June 21 through July 20, 2017. Exhibit 8 at 1-40. At her last session, she reported experiencing "shooting pain down her arm" earlier that day when reaching backwards to give directions. *Id.* at 1.

The most recent medical record filed is from a July 25, 2017 visit to Dr. Fulton. At that visit, petitioner reported continued pain, especially with certain motions, but improving strength. Exhibit 12 at 6. She added, however, that her current pain was much improved from the pain she experienced prior to her surgery. *Id.* Dr. Fulton instructed petitioner to work to continue her HEP and indicated he would see her "on an as needed basis." *Id.* at 7.

[9] A bursectomy is "excision of a bursa." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY at 264 (32th ed. 2012).

[10] Like Exhibits 5 and 7, petitioner did not label the individual pages in Exhibit 6 with exhibit and page numbers. *See supra* notes 6 & 8. Thus, the undersigned will use the page number listed in the CM/ECF heading to identify the particular page referenced in Exhibit 6.

III. Party Contentions

As an initial matter, respondent argues petitioner has not established that she received the vaccination alleged as causal in her right arm. Respondent's Rule 4(c) Report ("Res. Report"), filed Mar. 13, 2018, at 5 (ECF No. 36). Respondent further argues that, even if the site of vaccination can be established, petitioner has not provided sufficient evidence to support her SIRVA claim. *Id.* at 5-6.

Although respondent acknowledges that this petition was filed prior to the inclusion of SIRVA on the Table, he nonetheless urges that the Qualifications and Aids to Interpretation ("QAI") for SIRVA should be considered instructive regarding the criteria for determining whether a SIRVA exists.[11] Res. Report at 6. Stressing that the symptoms of SIRVA include limited ROM as well as shoulder pain,[12] respondent asserts that "the most contemporaneous medical records do not establish that the onset of

[11] Effective for petitions filed beginning on March 21, 2017, SIRVA is an injury listed on the Table. *See* National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Final Rule, 82 Fed. Reg. 6294 (Jan. 19, 2017); National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Delay of Effective Date, 82 Fed. Reg. 11321 (Feb. 22, 2017) (delaying the effective date of the final rule until March 21, 2017). The QAI for SIRVAs states:

> *Shoulder injury related to vaccine administration (SIRVA).* SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time frame;
>
> (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
>
> (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10) (2017).

[12] Respondent quotes the following portion of the SIRVA QAI, italicizing the portion referring to limited range of motion: "SIRVA manifests as shoulder pain *and limited range of motion* occurring after the administration of a vaccine intended for intramuscular administration in the upper arm." Res. Report at 6 (quoting 42 C.F.R. § 100.3(c)(10)(emphasis added)).

petitioner's pain or limitation of motion occurred within forty-eight hours of vaccination." *Id.* (citing 42 C.F.R. § 100.3(c)(10)(i)-(iv)). Respondent argues that limitations in petitioner's ROM were not documented until three months after vaccination. *Id.* at 6-7. While acknowledging the onset of petitioner's shoulder pain was described as acute, respondent maintains petitioner has not established her pain occurred within 48 hours. *Id.* at 7.

In her motion for a ruling on the record, petitioner asserts the record establishes she received the influenza vaccination in her right arm. Pet. Motion at 9 (ECF No. 41). She further asserts that she "experienced right shoulder pain, as well as pain and difficulty with movement," within 48 hours of vaccination. *Id.* at 10. Finally, although not disputed by respondent, petitioner asserts she has suffered the residual effects of her injury for more than six months. *Id.* at 11. The affidavits and documentation filed by petitioner in early April 2018 echo these assertions. *See* Exhibits 9-11 (affidavits from petitioner and others), 13 (receipt for light weight vacuum cleaner dated January 9, 2018). In her affidavit, petitioner asserts that her shoulder pain started the day after vaccination. Exhibit 9 at ¶ 4.

In his response to petitioner's motion, respondent indicates that he stands by his objections as stated in his Rule 4(c) report. Respondent's Response to Petitioner's Motion for a Ruling on the Record ("Res. Response"), filed May 9, 2018, at 1 (ECF No. 42). Additionally, he argues that, because the additional evidence provided by petitioner is in the form of affidavits, a fact hearing is needed. *Id.*

IV. Legal Standard

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1). § 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. § 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id.*

In addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement,[13] a petitioner must establish that she suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. § 11(c)(1)(C). The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the

[13] In summary, a petitioner must establish that she received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of her injury for more than six months, died from her injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. *See* § 11(c)(1)(A)(B)(D)(E).

corresponding injuries, and the time period in which the particular injuries must occur after vaccination. § 14(a).

Because this petitioner's claim predates the inclusion of SIRVA on the Table, she must prove her claim by showing that her injury was caused-in-fact by the vaccination in question. § 11(c)(1)(C)(ii). The Federal Circuit has held that to establish causation, a petitioner must "prove . . . that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). The received vaccine, however, need not be the predominant cause of the injury. *Id.* at 1351.

The Circuit Court has indicated that a petitioner "must show 'a medical theory causally connecting the vaccination and the injury'" to establish that the vaccine was a substantial factor in bringing about the injury. *Shyface,* 165 F.3d at 1352-53 (quoting *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992)). The Circuit Court added that "[t]here must be a 'logical sequence of cause and effect showing that the vaccination was the reason for the injury.'" *Id.* The Federal Circuit subsequently reiterated these requirements in a three pronged test set forth in *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). Under this test, a petitioner is required

> to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Id. All three prongs of *Althen* must be satisfied. *Id.* Circumstantial evidence may be considered, and close calls regarding causation must be resolved in favor of the petitioner. *Id.* at 1280.

V. Findings of Fact

Before ruling on entitlement in this case, the undersigned must make the following factual determinations: (1) whether petitioner received her October 8, 2016 influenza vaccination in her injured right arm; and (2) when the onset of petitioner's pain and range of motion occurred. Additionally, the undersigned will address respondent's request for a fact hearing and examine whether a hearing is needed in this case.

When making these factual findings, the undersigned adheres to the preponderance of evidence standard set forth in Section 13(a)(1)(A). Under that

standard, the existence of a fact must be shown to be "more probable than its nonexistence." *In re Winship*, 397 U.S. 358, 371 (1970) (Harlan, J., concurring).

The undersigned considers the record as a whole, relying primarily on information provided in the contemporaneously created medical records. As the Federal Circuit has noted, it is appropriate for a special master to give greater weight to evidence contained in medical records created closer in time to the vaccination, even if the information is provided as part of a medical history. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993) (medical records are generally trustworthy evidence). The Circuit Court explained that

> Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events.

Id.

A. Site of Vaccination

In this case, the record of vaccination does not identify the arm in which the vaccination was administered. *See* Exhibit 1. Nevertheless, the records show that in the months following vaccination, petitioner consistently attributed her shoulder pain to the influenza vaccination she received in her injured right arm. There is no indication in any of the medical records filed that petitioner received the vaccination in her left, rather than right, arm.

For example, when petitioner first seeks treatment from her PCP, Dr. Fitzgibbon, less than a month after vaccination, she complains of pain in her right deltoid after receiving a flu shot. Exhibit 2 at 40. Dr. Fitzgibbon recorded that he observed point pain in the insertion area of petitioner's right deltoid in the medical record from that visit. *Id.* When seen by her orthopedist, Dr. Fulton, petitioner reported an acute onset of right shoulder pain after receiving the influenza vaccination at her workplace in early October 2015. Exhibit 3 at 11. In the report from her right shoulder MRI in December 2015, it is noted that petitioner had experienced shoulder pain since her flu vaccination in October.

The undersigned finds there is preponderant evidence to show that petitioner received the influenza vaccination alleged as causal in her right arm.

B. Onset of Symptoms

It appears that the onset of petitioner's pain and limited ROM occurred at different times. Thus, the undersigned will address these questions separately.

1. Pain

In the contemporaneously created medical records, petitioner consistently describes the onset of her pain as occurring after she received the influenza vaccination alleged as causal. Although respondent correctly observes that petitioner did not specifically indicate that her pain began within 48 hours of vaccination (Res. Report at 7), there is no entry in the medical records suggesting petitioner's onset pain was delayed. Furthermore, accounts provided by petitioner to her treating physicians point to an immediate onset.

When petitioner first sought treatment from her PCP, she reported "pain in her right deltoid, insertion into her shoulder, after a flu shot . . . first part of October." Exhibit 2 at 40. At her first appointment with her orthopedist, petitioner described her pain as "fairly acute" and present "ever since the injection." Exhibit 3 at 11. When initially evaluated at PT, petitioner presented with "[right] shoulder pain after flu shot in Oct. 2015". Exhibit 4 at 30.

In her affidavit, petitioner indicates her pain began a day after vaccination. Exhibit 9 at ¶ 4. The undersigned notes that this onset is consistent with the medical records which place onset as after the vaccine, and "fairly acute." Thus, the undersigned credits petitioner's assertion that the onset of her pain occurred the day after vaccination.

Therefore, onset was within 48 hours of vaccination. The undersigned finds there is preponderant evidence that the onset of petitioner's pain occurred within 48 hours of vaccination.

2. Limited ROM

From the information contained in the medical records, it appears that the onset of petitioner's limited ROM, occurred between one to three months after vaccination. When seen by Dr. Fitzgibbon on November 5, 2015, petitioner reported only pain, and Dr. Fitzgibbon observed that she had normal range of motion and strength. Exhibit 2 at 40. However, by the time petitioner saw Dr. Fulton on January 19, 2015, she had "limited active and passive motion of the right shoulder in all planes particularly forward flexion and external rotation." Exhibit 3 at 11.

In her affidavit, petitioner alleges pain with certain movements in October 2015 (Exhibit 9 at ¶ 4) but did not mention a loss in ROM until early 2016 (*id.* at ¶ 8). In their affidavits, others claim that, within one week of vaccination, petitioner had difficulty moving (Exhibit 11 at ¶ 6) or was unable to lift her right arm (Exhibit 10 at ¶ 5). However, this difficulty was not noted by Dr. Fitzgibbon on November 5, 2015. Additionally, in her motion, petitioner does not allege limited ROM but only "pain and difficulty with movement" within 48 hours of vaccination. Pet. Motion at 10.

The record, as it now stands, contains preponderant evidence that petitioner experienced pain, which most likely occurred with movement as well as at rest, within 48 hours of vaccination and suffered limited ROM, which most likely occurred in late 2015 or early 2016. There is not sufficient evidence, nor does petitioner allege, that the onset of petitioner's limited ROM occurred within 48 hours of vaccination. However, as the undersigned will discuss in Section V, a finding of reduced ROM within 48 hours is not required to prove causation.

C. Fact Hearing

Noting that petitioner's later provided evidence was in the form of sworn and notarized affidavits, respondent argues that a fact hearing is necessary "to judge the credibility and reliability of the fact-witness testimony." Res. Response at 1 (ECF No. 42). The undersigned disagrees.

A special master may conduct a hearing if "reasonable and necessary" (§ 12(d)(3)(B)(v)), but a hearing is not required. The Vaccine Rules specifically state that a special master "may decide a case on the basis of written submissions without conducting an evidentiary hearing." Vaccine Rule 8(d); *see Oliver v. Sec'y of Health v. Human Servs.*, 133 Fed. Cl. 341, 354 (2017) (holding "the decision whether to hold a hearing is within the discretion of the special master."), *aff'd*, --- F.3d ---, 2018 WL 3945586 (Fed. Cir. 2018); *D'Tiole v. Sec'y of Health & Human Servs.,* 132 Fed. Cl. 421, 433-434 (2017) (noting that a hearing is helpful to assess witness credibility or obtain information not already provided), *aff'd,* 726 F.App'x. 809 (Fed. Cir. 2018). "[A] special master is not required to allow every proposed witness to testify." *Skinner v. Sec'y of Health & Human Servs.*, 30 Fed. Cl. 402, 409 (1994).

The undersigned has determined there is sufficient evidence in the medical records filed to support the factual findings above. The additional information provided in the affidavits submitted corroborated the information contained in the medical records, and thus, does not change the undersigned's findings. Therefore, a fact hearing is not necessary in this case.

VI. Ruling on Entitlement

In order to receive compensation under the Vaccine Act, petitioner must prove causation by satisfying the three pronged test set forth in *Althen* by the preponderance of evidence standard required in the Vaccine Act. 418 F.3d at 1278. In *Althen,* the Federal Circuit described this standard "as one of proof by a simple preponderance, of 'more probable than not' causation." *Id.* at 1279.

Although the first and second prongs of *Althen* appear to be similar, these analyses involve different inquiries. *See Doe 93 v. Sec'y of Health & Human Servs.*, 98 Fed. Cl. 553, 566-67 (2011). The first prong focuses on general causation, whether the administered vaccine can cause the particular injury suffered by the petitioner, and the

second prong focuses on specific causation, whether the administered vaccine did cause the injury. *Pafford v. Sec'y of Health & Human Servs.,* 451 F.3d 1352, 1355-56 (Fed. Cir. 2006). This distinction "has been described as the 'can cause' vs. 'did cause' distinction." *Stapleton v. Sec'y of Health & Human Servs.*, No. 03-234V, 2009 WL 1456441, at *18 (Fed. Cl. Spec. Mstr. May 1, 2009).

A. First *Althen* Prong

In determining that petitioner has satisfied the first *Althen* prong, the undersigned takes judicial notice of the fact that respondent has added SIRVA after receipt of an intramuscularly administered seasonal influenza vaccine to the Table. Such recognition of the causal link between vaccine and injury has been held to support the establishment of the theory require by the first *Althen* prong. *See Doe 21 v. Sec'y of Health & Human Servs.,* 88 Fed. Cl. 178, 193 (2009), *rev'd on other grounds*, 527 Fed. Appx. 875 (Fed. Cir. 2013). In proposing this Table addition, respondent discussed the means by which this injury is caused. *See* National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 Fed. Reg. 45132, 45137 (July 29, 2015). Specifically mentioned as supporting this causal link are the two articles filed as Exhibits I-II. *Id.* Much of the evidence discussed in the proposed revisions, regarding the process involved in vaccine caused SIRVA injuries, is included in the QAI for SIRVAs. *Compare id. with* 42 C.F.R. § 100.3(c)(10).

Additionally, the undersigned notes that, prior to the adoption of the revised Table, which is effective for petitions filed on March 21, 2017 and later, respondent has conceded entitlement in numerous SIRVA cases, alleging causation by an intramuscularly administered influenza vaccine. *See, e.g.*, *Cothern v. Sec'y of Health & Human Servs.,* No. 14-574V, 2014 WL 6609687 (Fed. Cl. Spec. Mstr. Oct. 15, 2014); *MacLaughlin v. Sec'y of Health & Human Servs.,* No. 17-57V, 2018 WL 3030269 (Fed. Cl. Spec. Mstr. Mar. 16, 2018). Even after the revised Table became effective, respondent has continued to concede cases which may not meet the Table criteria, but in which respondent, nevertheless, believes causation has been established. *See, e.g., Buras v. Sec'y of Health & Human Servs.,* No. 17-1012V, 2018 WL 4042194 (Fed. Cl. Spec. Mstr. Apr. 13, 2018).

While recognizing petitioner has the burden to establish causation, the undersigned notes that respondent does not dispute the assertion that SIRVAs can be caused by an intramuscularly administered influenza vaccine (general causation) and argues only that the influenza vaccination received by petitioner did not cause her injury (specific causation).

The undersigned finds the evidence discussed above comprises preponderant evidence sufficient to show that the seasonal influenza vaccine, when administered intramuscularly, can cause SIRVA. General causation is established, and petitioner has satisfied the first *Althen* prong.

B. Second and Third *Althen* Prongs

Although petitioner's claim does not constitute a Table Injury, the undersigned finds the QAI criteria for SIRVA to be informative when determining if petitioner has shown the influenza vaccination she received caused her injury in an appropriate time frame sufficient to establish a proximate temporal relationship between vaccination and injury. The four criteria listed in the QAI are as follows:

> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
> (ii) Pain occurs within the specified time frame;
> (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
> (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10)(i)-(iv).

The undersigned finds that all four criteria are satisfied by preponderant evidence in this case. As noted above, petitioner had no history of pain or inflammation in her right upper arm or shoulder prior to vaccination which would explain the pain she experienced after vaccination. Approximately 18 months prior to vaccination, in April 2014, petitioner suffered some numbness in her arms and legs (primarily her left arm) which were attributed to a "fibromyalgia flair," but, one month later, she indicated her body aches and pain were gone. A month after that, petitioner mentioned right elbow and wrist tendonitis, but this condition was not mentioned again. Petitioner's fibromyalgia, noted in 2014, was listed as resolved in her medical records beginning in June 24, 2015, several months before vaccination.

In the record describing petitioner's complaint of right shoulder pain after vaccination, it was specifically noted that petitioner's pain was limited to her right upper arm and shoulder, and there is no indication of pain or limited ROM in petitioner's left arm or shoulder. As the undersigned determined above, petitioner's shoulder pain occurred within 48 hours of vaccination which is the time frame specified for SIRVAs on the Table. There is no evidence in the medical records pointing to any other condition or abnormality which would explain petitioner's symptoms. Thus, petitioner has satisfied all four criteria.

In addition to these four criteria, language found at the beginning of the SIRVA section of the QAI appears to require that a petitioner manifest both pain and limited

ROM. This language is as follows: "SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm." 42 C.F.R. § 100.3(c)(10). The medical records show that, in this case, petitioner suffered from both pain and limited ROM. There is preponderant evidence to show petitioner has satisfied what could be deemed an additional requirement in the QAI.

Although not explicitly stated, respondent appears to be arguing that petitioner's pain and limited ROM must occur within 48 hours of vaccination before an injury would qualify as a Table SIRVA. Res. Report at 6. The undersigned finds that only petitioner's pain is required to have occurred within 48 hours of vaccination.

Even if the QAI language regarding the symptoms seen in SIRVAs equates to an additional requirement, that a petitioner suffer limited ROM as well as pain, there is nothing to require that the manifestation of limited ROM occur within 48 hours of vaccination. Contained within the four specifically enumerated criteria is a requirement that petitioner's pain occur within 48 hours. 42 C.F.R. § 100.3(c)(10)(ii). Additionally, petitioner's pain and limited ROM must be limited to the shoulder in which the vaccination was administered. 42 C.F.R. § 100.3(c)(10)(iii). There is, however, no requirement regarding the timing of the onset of the limited ROM.

For all Table injuries, the first symptom or manifestation of onset must fall within the period specified for that vaccine and injury. 42 C.F.R. § 100.3(a). For all SIRVAs, this period is 48 hours after vaccination. *See, e.g.,* 42 C.F.R. § 100.3(a)(XIV)(B) (for the requirement regarding timing applicable for a SIRVA after receipt of a seasonal influenza vaccination). However, this requirement applies only to the onset or first symptom of the Table injury. There is no requirement that all symptoms or a specific symptom occur within this time frame unless stated as a requirement in the QAI. As already discussed, for SIRVAs, pain is the only symptom required to occur within the time frame specified on the Table.

The undersigned finds the evidence discussed in this section qualifies as preponderant evidence to show the influenza vaccination administered to petitioner caused her shoulder injury within the time frame required. Specific causation is established, and petitioner has satisfied the second and third *Althen* prongs.

VII. Conclusion

The undersigned **GRANTS petitioner's motion for a ruling on the record.** Based on the complete record in this case and in light of the reasons discussed above, **the undersigned finds that petitioner is entitled to compensation in this case.**

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Chief Special Master